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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/051,286 | 01/22/2002 | Mary F. Parker | TAMC00-25 01 | 4762 |

27370 7590 11/16/2005

OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

EXAMINER

ROY, BAISAKHI

ART UNIT PAPER NUMBER

3737

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Talk

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/051,286 | PARKER ET AL. | |
| | Examiner | Art Unit | |
| | Baisakhi Roy | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/23/05 with respect to claims 1-4 as being anticipated by Bambot et al. (20030135122) have been fully considered but they are not persuasive. With respect to claims 1-4, Bambot et al. teach all the elements including normalization of the individual fluorescence spectral signals where ratios at multiple fluorescence emission wavelengths were determined ([0127], [0166-0171]) and where hyperspectral imaging is used to implement the invention [0039], [0176], and claim 57). Therefore, Bambot et al. do mention normalization of data in the context of hyperspectral imaging data. Applicant's arguments with respect to rejection of claim 2 under 35 U.S.C. § 112, first and second have been fully considered and are persuasive. Therefore this rejection has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1-5, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Bambot et al. (2003/0135122). Bambot et al. disclose a method and apparatus including a computer program for generating a two dimensional histological map of a cervix from a 3-dimensional hyperspectral data cube by scanning the cervix (fig. 60A/B, [0178], claim 57). Bambot et al. teach executing said method with an input processor (fig. 1 # 44) constructed to normalize the fluorescence spectral signals ([0130] [0131] [0142] [0151], extract pixel data, compress, assign tissue classification to the pixel data, and generate a two dimensional image of the cervix from the compressed data which includes color-coded regions representing specific tissue classifications of the cervix ([0115] [0151] [0154-0157] [0168-0171] [0175-0177], figs. 13-56).

2. Claims 5, 6, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Bambot et al. (2004/0147843). Bambot et al. disclose a method and apparatus using hyperspectral imaging ([0076] [0136]) to generate a three dimensional hyperspectral data cube by scanning the cervix of the subject with ultraviolet light, where the data cube comprises a plurality of two-dimensional fluorescence spectral signals (abstract, [0099]), normalizing variations in the peak magnitude of the fluorescence spectral signals collected from the hyperspectral data cube and comprises dividing each spectrum of the data cube by an area under the respective spectrum ([0104-0108]), extracting pixel data from the spectral signals that is indicative of cervical tissue

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classification ([0135]), and an image processor in communication with a classifier that generates a two-dimensional image of the cervix from the pixel data, which includes color-coded regions representing specific tissue classifications of the cervix ([0125-0126]).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Bambot et al. Yang et al. disclose an apparatus and computer-based method for generating a two dimensional histological map of a biological specimen from a 3-dimensional hyperspectral data cube (abstract, col. 1 lines 52-60, col. 15 lines 42-56). Yang et al. further teach executing said procedure by normalizing fluorescence spectral signals, extracting pixel data from the spectral signals, compressing the extracted pixel data, and classifying tissue into color-coded regions (col. 2 lines 14- 67, col. 3 lines 1-62, col. 9 lines 12-47, col. 10 lines 49-67, col. 11 lines 39-58, col. 13 lines 36-53). Yang et al. however do not explicitly teach applying said method to cervical tissue. In the same field of endeavor, Bambot et al. disclose a method an apparatus including a computer program for generating a two dimensional histological map of a cervix which includes color-coded regions representing specific tissue classifications of

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the cervix from a 3-dimensional hyperspectral data cube by scanning the cervix, as set forth above (fig. 60A/B, ([0115] [0151] [0154-0157] [0168-0171] [0175-0178], figs. 13-56, claim 57). It would have therefore been obvious to one of ordinary skill in the art to use the cervical tissue based teaching by Bambot et al. to modify the teaching by Yang et al. for the purpose of generating a two-dimensional histological map of a cervix from a 3-dimensional hyperspectral data cube.

5. Claims 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bambot et al. ('122) in view of Flateley et al. (6859275). Bambot et al. teach the extraction of meaningful data indicative of cervical tissue classification ([0151]) but do not explicitly teach performing wavelet transform techniques to generate a wavelet data matrix. In the same field of endeavor, Flateley et al. (6859275) disclose an apparatus and method for conducting hyperspectral imaging of tissue samples (fig. 32, 34, col. 19 lines 36-43, col. 22 lines 1-43, col. 24 lines 10-30). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Flateley et al. to modify the teaching by Bambot et al. for the purpose of enabling display of only relevant or meaningful data (col. 24 lines 15-25).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,167,297 – detecting, localizing, and targeting internal sites in vivo using optical contrast agents.

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6,678,398 – dual mode real-time screening and rapid full-area selective spectral, remote imaging and analysis device and process.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.R.

BR


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